## Office Action Summary

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Application No. 09/825,517

Applicant(s)

Rondon

Examiner

Ungar

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	s on the cover sheet with the correspondence address
Period for Reply	TTO EVEIDE MONTHUS FROM
A SHORTENED STATUTORY PERIOD FOR REPLY IS SETHE MAILING DATE OF THIS COMMUNICATION.	T TO EXPIRE <u>one</u> MONTH(S) FROM
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a).	n no event, however, may a reply be timely filed after SIX (6) MONTHS from the
mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within	
<ul> <li>If NO period for reply is specified above, the maximum statutory period will apply</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause</li> </ul>	
<ul> <li>Any reply received by the Office later than three months after the mailing date of earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	
Status	
1) Responsive to communication(s) filed on Apr 3, 2	
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This ac	ction is non-final.
3) Since this application is in condition for allowance closed in accordance with the practice under Ex p	except for formal matters, prosecution as to the merits is arte Quayle, 1935 C.D. 11; 453 O.G. 213.
Disposition of Claims	
4) 💢 Claim(s) <u>1-30</u>	is/are pending in the application.
4a) Of the above, claim(s)	is/are withdrawn from consideration.
5)  Claim(s)	is/are allowed.
6) Claim(s)	is/are rejected.
7)  Claim(s)	is/are objected to.
8) 💢 Claims <u>1-30</u>	are subject to restriction and/or election requirement.
Application Papers	
9) $\square$ The specification is objected to by the Examiner.	
10) The drawing(s) filed on is/ard	e a) $\square$ accepted or b) $\square$ objected to by the Examiner.
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See 37 CFR 1.85(a).
11) The proposed drawing correction filed on	is: a) $\square$ approved b) $\square$ disapproved by the Examiner.
If approved, corrected drawings are required in reply	to this Office action.
12) The oath or declaration is objected to by the Exam	iner.
Priority under 35 U.S.C. §§ 119 and 120	
13) $\square$ Acknowledgement is made of a claim for foreign $p$	priority under 35 U.S.C. § 119(a)-(d) or (f).
a) □ All b) □ Some* c) □ None of:	
1. Certified copies of the priority documents have	ve been received.
2.   Certified copies of the priority documents have	
3. Copies of the certified copies of the priority of	locuments have been received in this National Stage
application from the International Bure *See the attached detailed Office action for a list of the	
14) Acknowledgement is made of a claim for domestic	priority under 35 U.S.C. § 119(e).
a) $\square$ The translation of the foreign language provision	al application has been received.
15) $\square$ Acknowledgement is made of a claim for domestic	priority under 35 U.S.C. §§ 120 and/or 121.
Attachment(s)	
1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) Other:

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1. Claims 1-30 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

- 2. It is noted that claim 5 as currently constituted is dependent upon claim 3. However, the dependency is improper because claim 5 does not further limit claim 3 and thus, if examined would be rejected under 35 USC 112 fourth paragraph. Further, a review of the claims drawn to recombinant bacteriophage expressing exogenous DNA encoding a CEA binding polypeptide reveals no such improper dependency. Therefore in the interests of compact prosecution, rather than withdrawing claim 5 from consideration, it will be assumed for examination purposes that claim 5 was meant to be dependent upon claim 2. Appropriate correction is required
- 3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups 1-12,096,000. Claims 1,3, 4, 9, 11-13 are drawn to a polypeptide having the ability to bind CEA comprising SEQ ID NO:110 wherein each of

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the eight X's in SEQ ID NO:110 is defined by amino acids ranging from groups of three to fifteen, classified in Class 530, subclass 300+. It is noted that the number of polypeptides encompassed by the claim is 12,096,000. The analysis to take into account each of the polypeptides encompassed by this claim is N of X4 x N of X5 x N of X6 x N of X7 x N of X8 x N of X9 x N of X10 x N of X11. Thus 4 x 8 x 14 x 10 x 15 x 4 x 3 x 15 = 12,096,000. Applicant is required to elect a single specific sequence for examination from the 12,096,000 claimed. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined. Claims 3, 4, 9,11-13 will be examined as they are drawn to the elected Group.

Groups 12,096,001 - 528,356,537,600. Claims 2, 5-8, 10, 12, 13 are drawn to a polypeptide having the ability to bind CEA comprising SEQ ID NO:111 wherein each of the fourteen X's in SEQ ID NO:111 is defined by amino acids ranging from groups of one to fifteen, classified in Class 530, subclass 300+. It is noted that the number of polypeptides encompassed by the claim is 528,353,280,000. The analysis to take into account each of the polypeptides encompassed by this claim is N of X1 x N2 of X3 x N of X4 x N of X5 x N of X6 x N of X7 x N of X8 x N of X9 x N of X10 x N of X11 x N of X12 x N of X13 x N of X14. Thus 4 x 1 x 7 x 4 x 8 x 14 x 10 x 15 x 4 x 3 x 15 x 8 x 13 x 15 = 528,344,441,600. Applicant is required to elect a single specific sequence for examination from the 528,344,441,600 claimed. It is further noted, for Applicant's convenience, that this is not a species

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**election requirement** but rather a requirement for election of the specific group to be examined. Claims 5-8, 10, 12, 13 will be examined as they are drawn to the elected Group.

4. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 528,356,537,601. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of colon cancer, classified in Class 435, subclass 4+. Applicant is required to elect a single specific detecting sequence for examination. It is further noted, for

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Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Group 528,356,537,602. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of breast cancer, classified in Class 435, subclass 4. Applicant is required to elect a single specific detecting sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Group 528,356,537,603. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of lung cancer, classified in Class 435, subclass 4. Applicant is required to elect a single detecting sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Group 528,356,537,604. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of cervical cancer, classified in Class 435, subclass 4. Applicant is required to

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elect a single specific detecting sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Group 528,356,537,605. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of ovarian cancer, classified in Class 435, subclass 4. Applicant is required to elect a single specific detecting sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Group 528,356,537,606. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of stomach cancer, classified in Class 435, subclass 4. Applicant is required to elect a single specific detecting sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Group 528,356,537,607. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of

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bladder cancer, classified in Class 435, subclass 4. Applicant is required to elect a single specific detecting sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Group 528,356,537,608. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of pancreatic cancer, classified in Class 435, subclass 4. Applicant is required to elect a single specific detecting sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Group 528,356,537,609. Claims 14-18 are drawn to a method of detecting CEA using a labeled polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of esophageal cancer, classified in Class 435, subclass 4. Applicant is required to elect a single specific detecting sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

5. It is noted that the claims of the instant application have been determined to include linking claims. The restriction requirement among the linked inventions is

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subject to the nonallowance of the linking claim(s), claims 19. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 528,356,537,610. Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the CEA-associated disease is colon cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single specific treating sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

**Group 528,356,537,611.** Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide

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of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the CEA-associated disease is breast cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single specific treating sequence for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

Group 528,356,537,612. Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the CEA-associated disease is lung cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single specific treating sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Group 528,356,537,613. Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the detecting step is indicative of cervical cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single detecting sequence for examination. It is further noted, for Applicant's convenience, that this is

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**not a species election requirement** but rather a requirement for election of the specific group to be examined.

Group 528,356,537,614. Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the CEA-associated disease is ovarian cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single specific treating sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Group 528,356,537,15. Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the CEA-associated disease is stomach cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single specific treating sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Group 528,356,537,616. Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600

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polypeptides, each of which is a distinct invention, see analysis above, wherein the CEA-associated disease is bladder cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single specific treating sequence for examination. It is further noted, for Applicant's convenience, that **this is not a species election requirement** but rather a requirement for election of the specific group to be examined.

Group 528,356,537,617. Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the CEA-associated disease is pancreatic cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single specific treating sequence for examination. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Group 528,356,537,618. Claims 19-23 are drawn to a method of treating a CEA associated diseases comprising administering a conjugated polypeptide of claims 1-11. It is noted that claims 1-11 are drawn to 528,356,537,600 polypeptides, each of which is a distinct invention, see analysis above, wherein the CEA-associated disease is esophageal cancer, classified in Class 514, subclass 2+. Applicant is required to elect a single specific treating sequence for examination. It is further noted, for Applicant's convenience,

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that this is not a species election requirement but rather a requirement for election of the specific group to be examined.

Group 528,356,537,619. Claims 24 and 27 are drawn to a recombinant bacteriophage expressing exogenous DNA encoding a CEA binding polypeptide, classified in Class 536, subclass 23.1 and Class 435, subclass 320.1. It is noted that the number of recombinant bacteriophage encompassed by the claim is 12,096,000, as determined by the method of analysis above. Applicant is required to elect a single bacteriophage expressing a single specific sequence for examination from the 12,096,000 claimed. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for election of the specific group to be examined. Claim 27 will be examined as it is drawn to the elected Group.

Group 528,356,537,620. Claims 25-26, 28-30 are drawn to a recombinant bacteriophage expressing exogenous DNA encoding a CEA binding polypeptide, classified in Class 536, subclass 23.1 and Class 435, subclass 320.1. It is noted that the number of recombinant bacteriophage encompassed by the claim is 528,353,280,000 as determined by the method of analysis above. Applicant is required to elect a single bacteriophage expressing a single specific sequence for examination from the 528,344,441,600 claimed. It is further noted, for Applicant's convenience, that this is not a species election requirement but rather a requirement for

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election of the specific group to be examined. Claims 26, 28-30 will be examined as they are drawn to the elected Group.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions 1 through 12,096,000 as disclosed are chemically distinct, unrelated in structure, made by different methods and are therefore distinct inventions.

Inventions 1 through 12,096,000 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for binding CEA and can be used in other combinations comprising therapeutic or labeling reagents. Thus the claims are distinct as required by MPEP 806.05©).

Inventions 12,096,001 - 528,356,537,600 as disclosed are chemically distinct, unrelated in structure, made by different methods and are therefore distinct inventions.

Inventions 12,096,001 - 528,356,537,600 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that

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(1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for binding CEA and can be used in other combinations comprising therapeutic or labeling reagents. Thus the claims are distinct as required by MPEP 806.05©).

Inventions 528,356,537,619 through 528,356,537,620 as disclosed are chemically distinct, unrelated in structure, made by different methods and are therefore distinct inventions.

Inventions 528,356,537,619 through 528,356,537,620 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for expressing exogenous DNA encoding a CEA binding polypeptide and can be used in other combinations

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for producing different CEA binding polypeptides. Thus the claims are distinct as required by MPEP 806.05©).

Inventions 528,356,537,601 through 528,356,537,609 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. and/or schedules used, response variables, and criteria for success.

Inventions 528,356,537,601 through 528,356,537,609 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination polypeptide as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for labeling CEA/detecting cancer and can be used in other combinations comprising labeling reagents. Thus the claims are distinct as required by MPEP 806.05©).

Inventions 528,356,537,610 through 528,356,537,618 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. and/or schedules used, response variables, and criteria for success.

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Inventions 528,356,537,610 through 528,356,537,618 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05©)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination polypeptide as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for treating a CEA associated disease/cancer and can be used in other combinations comprising therapeutic reagents. Thus the claims are distinct as required by MPEP 806.05©).

The inventions of Groups 1 - 528,356,537,600 and 528,356,537,601-528,356,537,618 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see MPEP § 806.05(h)]. In the instant case the polypeptide product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 528,356,537,619 through 528,356,537,620 and Groups 528,356,537,601-528,356,537,618 are not at all related because the

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recombinant bacteriophage of Groups 528,356,537,619 through 528,356,537,620 is not used in any of the methods of Groups 528,356,537,601-528,356,537,618.

- 7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar

Primary Patent Examiner

August 21, 2003

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Total number of pages: 1

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